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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,887	03/29/2002	Bruce M. Boman	1657/1022	2568

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EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 08/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,887	BOMAN ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-45 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a continuation of U.S. Application Serial Number PCT/US00/21606.

Claims 1-45 are currently pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

1-17. Claims 1-9, 11, 14, 21-22, 34-36 and 45, respectively drawn to the nucleic acid molecule of SEQ ID NO: 27, 29, 31, 33, 35, 37, 38, 40, 42, 44, 46, 48, 50, 51, 52, 60 or 61, a nucleic acid that hybridizes to the respective nucleic acid, test kits comprising the respective nucleic acid and a pharmaceutical composition comprising the respective nucleic acid, classified in class 536, subclass 23.5.

18-34. Claim 10, respectively drawn to a transgenic animal having a transgene comprising a nucleic acid molecule of SEQ ID NO: 27, 29, 31, 33, 35, 37, 38, 40, 42, 44, 46, 48, 50, 51, 52, 60 or 61, classified in class 800, subclass 13.

35- 51. Claims 12, 13 and 37-40, respectively drawn to an isolated peptide comprising a sequence of at least 25 amino acids encoded by the nucleic acid molecule of SEQ ID NO: 27, 29, 31, 33, 35, 37, 38, 40, 42, 44, 46, 48, 50, 51, 52, 60 or 61 and the corresponding polypeptide of SEQ ID NO: 28, 30, 32, 34, 36, 41, 43, 45, 47 or 49, classified in class 530, subclass 324.

52. Claims 15-17, drawn to an oligonucleotide array comprising at least 10 different oligonucleotides that hybridize to a nucleic acid molecule selected from the nucleic acid molecules of SEQ ID NO: 27, 29, 31, 33, 35, 37, 38, 40, 42, 44, 46, 48, 50, 51, 52, 60 and 61, classified in class 536, subclass 24.3.

53-69. Claims 18, 19 and 23, respectively drawn to an antibody immunoreactive with an isolated peptide comprising a sequence of at least 25 amino acids encoded by the nucleic acid molecule of SEQ ID NO: 27, 29, 31, 33, 35, 37, 38, 40, 42, 44, 46, 48, 50, 51, 52, 60 or 61 and the corresponding polypeptide of SEQ ID NO: 28, 30, 32, 34, 36, 41, 43, 45, 47 or 49, classified in class 530, subclass 387.1.

70-86. Claims 70-86, respectively drawn to antisense nucleotides which hybridize to the nucleic acid molecule of SEQ ID NO: 27, 29, 31, 33, 35, 37, 38, 40, 42, 44, 46, 48, 50, 51, 52, 60 or 61, classified in class 536, subclass 24.5.

87-103. Claims 24-26, 29 and 41-42, respectively drawn to a method for detecting a cell expressing the nucleic acid molecule of SEQ ID NO: 27, 29, 31, 33, 35, 37, 38, 40, 42, 44, 46, 48, 50, 51, 52, 60 or 61 by detecting the nucleic acid molecule, classified in class 435, subclass 6.

104-120. Claims 27-28, 30, 34 and 43-44, respectively drawn to detecting the expression in a cell a polypeptide encoded by the nucleic acid molecule of SEQ ID NO: 27, 29, 31, 33, 35, 37, 38, 40, 42, 44, 46, 48, 50, 51, 52, 60 or 61, classified in class 435, subclass 7.1.

121-137. Claim 32, respectively drawn to a method for detecting a mutation in a nucleic acid that hybridizes to the nucleic acid molecule of SEQ ID NO: 27, 29, 31, 33, 35, 37, 38, 40, 42, 44, 46, 48, 50, 51, 52, 60 or 61, classified in class 435, subclass 6.

138-154. Claim 33, respectively drawn to a method of detecting an agent that alters the expression of the nucleic acid molecule of SEQ ID NO: 27, 29, 31, 33, 35, 37, 38, 40, 42, 44, 46, 48, 50, 51, 52, 60 or 61, classified in class 435, subclass 7.

155-171. Claim 35, respectively drawn to a pharmaceutical composition comprising an agent that alters the expression of the nucleic acid molecule of SEQ ID NO: 27, 29, 31, 33, 35, 37, 38, 40, 42, 44, 46, 48, 50, 51, 52, 60 or 61, classified in class 536, subclass 24.5.

NOTE: While a number of Groups overlap with one another in terms of the claims included in the group, each claim in a Group will only be examined to the extent that it reads upon the elected nucleic acid or polypeptide of the compound, composition or method.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-17 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different nucleic acid molecules having a nucleotide sequence distinct from the others. Each nucleic acid of Groups 1-17 can be isolated without regard to any of the other nucleic acids.

Inventions 18-34 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different transgenic animals that are transgenic for nucleic acid molecules having a nucleotide sequence distinct from the others. Each transgenic animal of claims 18-34 expresses a different polypeptide product.

Inventions 35-51 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different polypeptide molecules having an amino acid sequence distinct from the others. Each polypeptide of Groups 18-34 can be isolated without regard to any of the other polypeptides.

Inventions 1-17 and 35-51 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to compounds composed of different basic building blocks. The nucleic acids of Groups 1-17 can be isolated without regard to the polypeptides of Groups 18-34 and *vice versa*.

Inventions 1-17 and 52 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are divergent in that the probes and nucliec acid molecules of Groups 1-17 are useful for the detection of the expression of a single gene, while the arrays of Group 52 are used for creating a profile of a cell type.

Inventions 35-51 and 53-69 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are patentably distinct because the protein can be made or purified without regard to the antibody and has the separate utility of being useful for receptor binding assays..

Inventions 1-17 and 70-86 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are distinct because the nucleic acids of Groups 1-17 are useful as probes or for the recombinant production of peptides, while the antisense molecules of Groups 70-86 are useful only as inhibitors of transcription.

Inventions 1-17 and 87-103 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid molecules of Groups 1-17 have the separate utility of recombinant polypeptide production.

Inventions 35-51 and 104-120 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the polypeptides of Groups 35-51 have the separate utility of being useful in receptor binding studies.

Inventions 87-103 and 121-137 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are patentably distinct because the method of Groups 87-103 is drawn to detecting the native products of the recited nucleic acid sequences, while the method of Groups 121-137 is drawn to the detection of mutants. Accordingly, the assays are drawn to the detection of different products.

Inventions 87-103 and 138-154 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are distinct because the method of Groups 87-103 is drawn to the detection of the nucleic acid molecule in a cell, while the method of claims 138-154 is drawn to the detection of agents that alter gene expression. Accordingly, the methods look for different products and have distinctly different endpoints.

Inventions 138-154 and 155-171 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the agents of claims 155-171 are identifiable by methods other than the method of claims 138-154.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to

final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
July 27, 2004

PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER